

Senate Bill No. 798

CHAPTER 444

An act to add Division 116 (commencing with Section 150200) to the Health and Safety Code, relating to pharmaceuticals.

[Approved by Governor September 30, 2005. Filed with
Secretary of State September 30, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

SB 798, Simitian. Prescription drugs: collection and distribution program.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This bill would authorize a county to establish, by ordinance, a repository and distribution program for purposes of distributing surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill would limit the program to pharmacies owned by or contracting with the county. It would require a county that elects to establish a repository and distribution program to establish procedures for, at a minimum, (1) establishing eligibility for medically indigent patients who may participate in the program, (2) ensuring that eligible patients are not charged for any medications provided under the program, (3) developing a formulary of appropriate medications for the program, (4) ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacy, and (5) ensuring the privacy of individuals for whom the medication was originally prescribed. The bill would authorize any drug manufacturer legally authorized under federal law to manufacture or sell pharmaceutical drugs, or a licensed health facility, pharmacy wholesaler, or pharmacy to donate medications pursuant to these provisions. Except in cases of noncompliance with the bill, bad faith, or gross negligence, the bill would prohibit certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the bill's provisions.

The people of the State of California do enact as follows:

SECTION 1. Division 116 (commencing with Section 150200) is added to the Health and Safety Code, to read:

DIVISION 116. SURPLUS MEDICATION COLLECTION AND DISTRIBUTION

150200. It is the intent of the Legislature in enacting this division to authorize the establishment of a voluntary drug repository and distribution program for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

150201. For purposes of this division, “medication” or “medications” means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

150202. Notwithstanding any other provision of law, a licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease, may donate unused medications under a program established pursuant to this division.

150203. Notwithstanding any other provision of law, a wholesaler licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code and a drug manufacturer that is legally authorized under federal law to manufacture and sell pharmaceutical drugs may donate unused medications under the voluntary drug repository and distribution program established by a county pursuant to this division.

150204. (a) A county may establish, by ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county pursuant to this division may participate in this program to dispense medication donated to the drug repository and distribution program.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a county-owned or county-contracted, licensed pharmacy.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a skilled nursing facility, shall have been under the control of staff of the skilled nursing facility.

(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program.

(e) A pharmacist shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in any of the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(j) Medication donated to the repository and distribution program shall be segregated from the pharmacy's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) The pharmacy shall keep complete records of the acquisition and disposition of medication donated to and dispensed under the repository and distribution program. These records shall be kept separate from the pharmacy's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000), of Division 2 of the Business and Professions Code), including being readily retrievable.

(l) Local and county protocols established pursuant to this act shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health and Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at their appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating county-owned or county-contracted pharmacy shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

150205. The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:

(a) A prescription drug manufacturer, wholesaler, governmental entity, county-owned or county-contracted licensed pharmacy, or skilled nursing facility.

(b) A pharmacist or health care professional who accepts or dispenses prescription drugs.

150206. The immunities provided in Section 150205 shall not apply in cases of noncompliance with this division, bad faith, or gross negligence.

150207. Nothing in this division shall affect disciplinary actions taken by licensing and regulatory agencies.